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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/670,168

09/25/2003

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EXAMINER

HOUSTON, ELIZABETH

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

12/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/670,168	Applicant(s) VARDI ET AL.	
	Examiner ELIZABETH HOUSTON	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8,13-15,19-23 and 28-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8,13-15,19-23 and 28-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Withdrawal of Finality

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn. As such, this office action replaces the previous action mailed on 10/06/08.

Priority

2. For the record, claims 4, 7, 17 and 22 claim subject matter that does not have support in the parent case (09/860,744), therefore they will not receive the benefit of the earlier filing date.

Drawings

3. The drawings were received on 12/05/08. These drawings are accepted in order to address the drawing objections addressed in the previous action.

Claim Rejections - 35 USC § 103

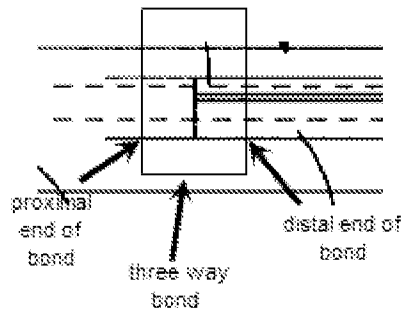
4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

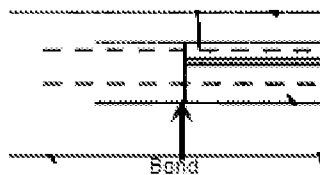
5. Claims 1-5, 8, 13-15, 19-23, 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (US 6,099,497).

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6. Adams discloses a catheter system (Fig. 14d) for positioning a stent (156) at a vessel bifurcation, the catheter system comprising: a catheter (120), the catheter comprising: a channel (134) having a main guidewire lumen extending from a distal end to a main exit port (C10:L18-24) located at a first distance from the distal end and configured to receive a main vessel guidewire (58); and a branch guidewire enclosure (136) positioned alongside said channel and configured to receive a branch vessel guidewire (60); and a stent (Fig. 7a, 64) having a lumen and a side opening (68) in a wall thereof said stent positioned on a distal portion of said channel, and wherein a distal portion of said branch guidewire enclosure is positioned through said lumen and exiting at said side opening (C11:L24-30), said branch guidewire enclosure extending proximally from said side opening of said stent to a branch exit port (C10:L18-24) located at a second distance from the distal end. Adams indicates that the branch exit port and the main exit port are located at equal distance from the distal end of the catheter (C10:18-24: *lumens extend to a point*). There is a balloon for expanding the stent and an inflation portion for inflating the balloon (124). Regarding claim 4, There is further a bond portion connecting the main exit port and the branch exit port to a proximal tube (bond portion can be arbitrarily chosen to be any portion that connects the ports to the tube). Regarding claim 13, there is three way bond coupling the distal end of the proximal tube to the proximal end of the first tube and to the proximal end of the second tube. The proximal end connects to the three way bond (proximal end of bond shown below) at a location spaced from where the distal portion connects to the three way bond (distal end of bond shown below).



With respect to claim 28, the bond has a proximal end (left side of junction) connecting to the distal end of the proximal tube and the bond has a distal end (right side of junction) connecting to the first and second distal tubes at the proximal ends of the first and second tubes.



7. With respect to the embodiment of Fig. 14D, Adams does not explicitly disclose that the branch guidewire enclosure is bonded to the channel *only* at said branch exit port or only at the three way bond. However, Adams does disclose different embodiments showing different modes for bonding the guidewire enclosure to the channel. For example: Figure 15a shows the branch guidewire enclosure is embedded in the balloon (C11:L49-55); Figure 16 shows enclosure bonded to the outside of the balloon (C12:L1-6); Figure 14d shows the enclosure bonded only at the balloon portion; Fig. 17 shows the enclosure is not bonded at the transition shaft or in the area of the balloon (C:L15-29); and Fig. 18 shows the enclosure is connected at the shaft 122 (C12:30-43). Therefore, it follows that Adams indicates that the mode of bonding the

enclosure to the catheter is a matter of obvious design choice and a person of ordinary skill would have good reason to pursue the known options within his or her technical grasp, such as a bond located only at the branch exit port or a bond located only at the three way bond such that the first and second distal tubes are detached outside of the bond, if it yields predictable results namely, a way of bonding a tubular enclosure to a catheter shaft. Furthermore, the instant disclosure describes this parameter as merely preferable (specification p7:L26-p8:L5) and does not describe it as contributing any unexpected result to the stent delivery device. As such this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

8. Regarding claims 5, 8, 20, 23 and 30; Adams discloses the claimed invention as stated above except for the dimensions locating the exit openings and the length of the guidewire. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary the size of the catheter and therefore the location of the exit ports and length of the guidewire depending on the size and location of the lumen in which it would be used. For instance catheter used on an infant would be significantly smaller than that used on a large adult. Additionally, a catheter that is being delivered to the aorta will be larger than one that is being delivered to the brain. Such a modification would have involved a mere change in the size of a component, and a change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955). Regarding claim 22, since it would a matter of obvious design choice in determining the location of the exit ports, it would be well within the skill

of the ordinary artisan to choose the location of the ports to be at (near) the three way bond. Regarding claim 28, since it would a matter of obvious design choice in determining the location of the exit ports, it would be well within the skill of the ordinary artisan to choose the location of the exit ports for the guidewires at the proximal end of the first and second distal tubes (for example as evidenced by Fig. 1b, Ischinger (US 6,682,556))

Response to Arguments

9. Applicant's arguments, see Remarks, filed 12/05/08, with respect to 1-5, 8, 13-23, 28-31 have been fully considered and are persuasive. The rejection of 10/06/08 has been withdrawn.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./

Examiner, Art Unit 3731

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731